JUL 18 2007

5 510(k) Summary as required by Section 807.92(c)

Submitter	Orthogem Limited BioCity Pennyfoot Street Nottingham NN1 1GF United Kingdom
Telephone	011 44 115 854 9486
Facsimilie	011 44 115 854 2808
Contact Person	Rod Ruston BSc RAC
Date Prepared	
Trade Name	TriPore HA TriPore BP90 TriPore BP15
Common Name	1)Synthetic, porous hydroxylapatite: TriPore HA 2)Synthetic, porous biphasic tricalcium phosphate/hydroxylapatite: TriPore BP90: nominal 90% HA with 10% tricalcium phosphate 3)Synthetic, porous biphasic tricalcium phosphate/hydroxylapatite TriPore BP15: nominal 15% HA with 85% tricalcium phosphate
Classification	Resorbable calcium salt bone void filler devices have been classified by the Orthopedics Device Panel as Class II Special Controls per 21 CFR 888.3045. Product code: MQV
Predicate Device	Orthovita Vitoss™
Device Description	TriPore HA is pure hydroxylapatite bone void filler, with a highly porous structure comprising three types of porosity which are interconnected: macropores (100 µm to 1-2mm), midipores (10-100 µm) and microspaces (1-10 µm). TriPore BP90 and TriPore BP15 are a biphasic tricalcium phosphate:hydroxylapatite. The (X) designates the nominal hydroxyapatite composition of the mixture. TriPore BP bone void filler has the same structure as TriPore HA. TriPore (HA or BP) is available in Blocks (D-shaped, cuboid and other shapes) and Granules (four different sizes).

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Intended Use	TriPore HA, TriPore BP90 and TriPore BP15 is intended to be packed into bone defects of the skeletal system (extremities, spine or pelvis) which are not intrinsic to the stability of the bony structure. These defects may be surgically created voids or from traumatic injury to the bone. This device can also be used for maxillofacial surgery for the reconstruction of the facial skeleton. The device gradually resorbs and is replaced with bone during the healing process. Rigid fixation techniques should be used in conjunction with this device.
Technical Characteristics and Substantial Equivalence	Both the predicate device, Vitoss and TriPore (HA and BP) share similar characteristics in that they are both calcium salt bone void fillers covered by 'Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device" (FDA Guidance Document 855, dated June 2, 2003). Both have a porous structure which promotes bone ingrowth. They are available in blocks or granules (TriPore) and morsels (Vitoss). They differ from each other in two main aspects: 1) the pore size and distribution 2) the material – Vitoss is manufactured from pure tricalcium phosphate. TriPore HA is manufactured from pure hydroxylapatite. TriPore BP is manufactured from a mixture of pure tricalcium phosphate and pure hydroxylapatite.
Determination of substantial equivalence (non-clinical data)	Orthogem has determined that TriPore is substantially equivalent to the predicate device on the basis of chemical composition tests on both devices as prescribed in the 'Class II Special Controls Guidance Document' referenced above. Secondly, TriPore itself complies with the requirements of the Special Controls Document referred to above.
Determination of substantial equivalence (animal data)	Animal studies making direct comparison against the predicate device concluded that at 24 weeks implant, TriPore implants were structurally more integral with interconnecting walls and bone present within the macro pores, midi pores and micro spaces.
Conclusions	Orthogem concludes that the non-clinical and animal tests discussed above demonstrate that TriPore is safe, effective and performs as well as or better than the predicate device.
Other information deemed necessary by the FDA	None more than that required by 'Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device" (FDA Guidance Document 855, dated June 2, 2003).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 2007

Orthogem Limited
% Mr. Rod Ruston
Project Manager
Biocity
Pennyfoot Street
Nottingham
NG1 1GF
United Kingdom

Re: K070132
Trade/Device Name: TriPore HA, TriPore BP90, TriPore BP15
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler
Regulatory Class: Class II
Product Code: MQV
Dated: June 18, 2007
Received: June 20, 2007

Dear Mr. Ruston:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

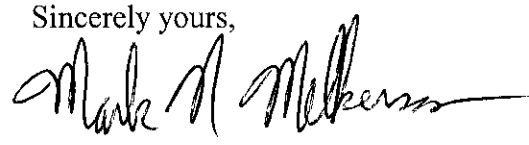
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276- 0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K070132

Device Name: TriPore HA, TriPore BP90, TriPore BP15

Indications For Use:

TriPore HA, TriPore BP90 and TriPore BP15 is intended to be packed into bone defects of the skeletal system (extremities, spine or pelvis) which are not intrinsic to the stability of the bony structure. These defects may be surgically created voids or from traumatic injury to the bone. This device can also be used for maxillofacial surgery for the reconstruction of the facial skeleton. The device gradually resorbs and is replaced with bone during the healing process. Rigid fixation techniques should be used in conjunction with this device.

Prescription Use: YES (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use: NO (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K070132